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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
NOAKES, SUZANNE MARIE	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/822,938	HSIAO ET AL.	
	Examiner	Art Unit	
	Suzanne M. Noakes, Ph.D.	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *54-59 and 61-76* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *54-59 and 61-76* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. The amendments filed 2 February 2006 have been entered. Applicants have cancelled claim 60. Claims 54-59 and 61-76 are pending and under examination.

Withdrawal of Rejections/Objections

2. The objection to claim 61 is hereby withdrawn in view of Applicant's amendments to the claim.

3. The 35 U.S.C. 112 2nd paragraph rejections of claims 54 and 60, as presented in Sections 6 and 7, of the previous Office action, respectively, are hereby withdrawn. The former because Applicants arguments are persuasive, the later because of said cancellation of the rejected claim.

4. The 35 U.S.C. 112 1st paragraph rejections, as presented in Sections 8-10 of the previous Office action is hereby withdrawn.

Response to Arguments

5. Applicant's arguments with respect to claims 54-59 and 61-76 have been considered but are moot in view of the new ground(s) of rejection.

New Rejections

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 54-59 and 61-74 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to methods of producing collagen monomers by fermenting collagen contain tissues with any microorganism (claims 54-59, 61-63 and 65-67) and from the genus *Bacillus* (claims 64 and 68-76), and subsequently adding enzymes/acid and precipitating out the monomeric form. Thus, the claims are drawn to an unlimited number of microorganisms used in the fermentation step, which run in the range of millions for the broad claims drawn to microorganisms (claims 54-59, 61-63 and 65-67) and the thousands for the more limited claims drawn to the genus *Bacillus* (claims 64 and 68-76). Thus, a skilled artisan will be required to determine which exact species of microorganism works at all in the claimed invention. Furthermore, the specification, does not allow the disclosure to the public and skilled artisan required in order to exactly reproduce the claimed invention. Thus, there is a considerable expectation that undue experimentation will be expected and thus the claims are not enabled.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some

experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

In the instant case, undue experimentation will be expected because Applicants have not even attempted to provide a single species of the claimed genus'. Rather, they have provided in the specification, that the genus' *Bacillus*, *Lactobacillus* and yeast will all work. The working examples simply state that "A field isolate Gram (+) bacterium, belonging to the genus Bacillus, was used in the fermentation process utilized to extract collagen from the tissues." (p. 19, 1st line, 1st paragraph). There are to date 193 different species of *Bacillus* and Applicants have not disclosed even a single species from this genus (see DSMZ document) which they used in their claimed invention. The problem in doing so, is that a skilled artisan is not going to know which species Applicants have used and thus may not be able to successfully reproduce

Applicants results of obtaining mostly collagen monomers because a skilled artisan will realize that not every microorganism will work with the claimed invention because each microorganism produces its own unique bi-products depending on whether it is an aerobe, obligate aerobe, anaerobe, obligate anaerobe or facultative anaerobe, *and* % oxygen environment and culture medium. For some organisms, this will mean that an environment that is strictly reducing will be achieved, for others, the complete opposite. Whether or not, however, each microorganism will produce the requisite enzymes that will successfully breakdown collagen is a matter which is left to be determine by the skilled artisan. In the case of *Bacillus,* while all species of this genus are Gram (+) aerobes, some grow at acidic pH's such as that of *Bacillus acidocaldarius* while others like *Bacillus subtilis* grow at neutral pH's. This may be an absolutely critical piece of information that Applicants have chosen not to disclose to the public and thus a skilled will necessarily have to perform undue experimentation in order to figure out which of the 193 species works the best and which one Applicants may or may not have used themselves. This leads a great deal of unpredictability as well, when it a skilled artisan has no idea which species to use, because there is no way even trying to guess which ones with similar characteristics to Applicants would produce the same sort of enzymes which ferment and degrade the collagen. Furthermore, Applicants recognition of the fact that different microorganisms produce different enzymes is apparent in the specification as on p. 4, 3rd sentence it is stated: "Microorganisms are capable of generating a wide array of molecules as end points to fermentation." But which end point is critical for the claimed invention is disclosed ambiguously at best.

The enablement requirement is clearly predicated on whether or not undue experimentation will be required, not how much experimentation, just simply that it is undue. In this case, it is evident that undue experimentation will necessarily be the case because Applicants have not disclosed in accordance with the 35 U.S.C. 112 1st paragraph statute because clearly the specification does not contain the manner and process of making the claimed invention, in such full, clear, concise, and *exact terms* so as to enable any person skilled in the art to which it pertains, to make and use the invention and they have not set forth the best mode contemplated by the inventor of carrying out his invention.

Conclusion

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzanne M. Noakes, Ph.D. whose telephone number is 571-272-2924. The examiner can normally be reached on Monday to Friday, 7.30am to 4.00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SMN
13 April 2006

ROBERT A. WAX
PRIMARY EXAMINER